NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHLOMO SPAR, individually and on behalf of all others similarly situated, Plaintiff, v. **CELSION CORPORATION, *et al.*,** Defendants.	Civil Action No. 20-15228 (ZNQ) (DEA) **OPINION**

QURAISHI, District Judge

This matter comes before the Court upon a Motion to Dismiss filed by Defendants Celsion Corporation, Michael H. Tardugno, Jeffery W. Church, and Nicholas Borys (collectively, "Defendants") (ECF No. 28). Defendants submitted a memorandum in support. ("Moving Br.," ECF No. 28-1). Additionally, Defendants submitted a Request for Judicial Notice. ("Notice Br.," ECF No. 28-5). Lead Plaintiff Milan Taraba filed Oppositions to the Motion to Dismiss and Request for Judicial Notice. ("Opp'n Br.," ECF No. 30; "Notice Opp'n Br.," ECF No. 31). Defendants filed Replies. ("Reply Br.," ECF No. 33; "Notice Reply Br.," ECF No. 34).

The Court has carefully considered the parties' submissions and decides the matter without oral argument pursuant to Federal Rule of Civil Procedure 78(b) and Local Civil Rule 78.1(b). For the reasons set forth below, Defendants' Motion and Request for Judicial Notice will be GRANTED.

I. BACKGROUND AND PROCEDURAL HISTORY

Plaintiffs represent a class of all persons and entities that purchased or otherwise acquired Celsion securities between the period of April 15, 2020 and July 13, 2020 ("Class Period"). (ECF No. 19, First Amended Complaint ("FAC") ¶ 1.) Lead Plaintiff Milan Taraba ("Taraba") purchased Celsion securities during the Class Period. (FAC. ¶ 15.) Defendant Celsion is a Delaware Corporation with its principal place of business in New Jersey. (FAC. ¶ 16.) Defendant Michael H. Tardugno ("Tardugno") is Celsion's Chief Executive Officer and President. (FAC. ¶ 17.) Tardugno is a member of the Board of Directors and is currently the Board's Chairman. *Id*. Defendant Jeffrey W. Church ("Church") is Celsion's Chief Financial Officer and an Executive Vice President. (FAC. ¶ 18.) Defendant Nicholas Borys ("Borys") is Celsion's Chief Medical Officer and an Executive Vice President who manages Celsion's clinical development and regulatory programs. (hereinafter referred to as Defendants) *Id*.

Celsion is an oncology company focused on advancing cancer treatments and associated technology, including DNA-based immunotherapies, next generation vaccines, and directed chemotherapies. (FAC. ¶ 26.) As such, Celsion developed ThermoDox, a heat-activated liposomal encapsulation of docurbicin to treat liver cancer or Hepatocellular Carcinoma. (FAC. ¶ 27.)

In 2013, Celsion conducted a clinical trial for ThermoDox titled HEAT. (FAC. ¶ 29.) The primary endpoint of the study was to measure the improvement in progression-free survival. (FAC. ¶ 27.) The study involved 701 patients and was a Phase III blinded clinical trial, which involved the administration of ThermoDox along with radiofrequency ablation ("RFA"), an electrical current produced by a radio wave that heats up a small portion of nerve tissue to destroy cancer cells. (FAC. ¶¶ 27–29.) On January 31, 2013, Celsion announced that the study failed to

meet its primary endpoint. (FAC. ¶ 29.) In efforts to improve the study, Celsion along with the National Institutes of Health ("NIH"), performed a post-hoc statistical analysis, and found that patients in the subgroup, which consisted of individuals who received both ThermoDox and at least 45 minutes of RFA, had a significantly better overall survival rate than those who only received RFA. (FAC. ¶ 30.) Celsion thereafter received approval by the U.S. Food and Drug Administration ("FDA") to design the OPTIMA trial, which would specifically test the efficacy of ThermoDox and RFA. (FAC. ¶ 33.) The primary endpoint of the OPTIMA trial was to increase overall survival. (FAC. ¶ 36.) Therefore, Celsion established an independent Data Monitoring Committee ("DMC") to: (1) analyze and report trial results to Celsion, (2) to issue interim and final efficacy analyses, and (3) to recommend whether to continue or stop the clinical trial. (FAC. ¶ 34.) The DMC was responsible for transmitting its first interim report to Celsion after 128 deaths, and its second interim report after 158 deaths. *Id*. The trial was to be concluded and a final report issued after 197 deaths. *Id*. In 2014, the OPTIMA clinical trial began, (FAC. ¶ 4), and throughout the trial Defendants expressed optimism. (FAC. ¶ 36.)

A. Defendants' Statements in 2016

1. During a quarterly conference call on May 16th, Defendants stated that "[w]e are pleased with the progress we have seen in the OPTIMA trial[.]" (FAC. ¶ 37.)
2. In a July 11th press release, Defendants stated that "the strength of the preclinical and clinical data reinforces our confidence in the potential of ThermoDox in HCC and for a successful trial outcome. We are extremely encouraged with the investigators' interest and enthusiasm with our approach." *Id*.
3. In an August 15th press release, Defendants stated that "data presentations and publications in multiple peer-reviewed forums continue to highlight the potential for a curative approach of ThermoDox plus optimized RFA." (FAC. ¶ 38.)
4. In a November 10th press release, Defendants expressed that the NIH post-hoc analysis of the HEAT study subgroup as indicating "mounting support for the OPTIMA study." (FAC. ¶ 39.)

5. During a quarterly conference call on November 11th, Defendants stated that "data supporting the OPTIMA study [is] stronger … now for over four years, no matter whether conducted by Celsion or independently scrutinized." *Id*.
6. In a December 16th press release, Defendants called the data from the Chinese cohort of the HEAT trial, "remarkable." (FAC. ¶ 40.)

B. Defendants' Statements in 2017

1. In a March 16th press release, Defendants stated that there is "superb execution" of their "ground-breaking" OPTIMA trial. (FAC. ¶ 41.)
2. In a May 12th press release, Defendants repeated the "ground-breaking" claim. *Id*.
3. During a quarterly conference call on May 12th, Defendants stated that "we believe our many analyses that support the OPTIMA study, or if you have any confidence in the independent opinion of the National Institutes of Health, then you should have to agree that the chance of success with our OPTIMA study is as good as it gets in our industry." (FAC. ¶ 42.)
4. In a September 27th press release, Defendants stated that "investigators fully recognize the value of the findings from the HEAT Study." (FAC. ¶ 43.)
5. During an earnings conference call, on November 14th, Defendants stated that, "hypothesis [for the success of the OPTIMA trial] is supported with some of the most persuasive and productive prospective and retrospective data that has ever been taken in my experience for a clinical trial." (FAC. ¶ 44.)

In 2018, during a quarterly conference call on August 14th, Defendants stated that "the evidence supporting the thesis for the OPTIMA study is overwhelming" and that if successful, ThermoDox would be "one of the most important new drugs in oncology in a generation, if not our lifetime." (FAC. ¶ 45.) Following, on August 5, 2019, the prescribed 128 deaths had been reached for the DMC's first interim analysis. (FAC. ¶ 46.) On November 1, 2019, the DMC performed its first interim analysis, and the DMC recommended continuing the OPTIMA clinical trial. (FAC. ¶ 48.)

C. Defendants' Statements in 2019

1. During a quarterly conference call on August 15th, Defendants stated that the result of the HEAT study subgroup were "nothing short of remarkable. (FAC. ¶ 47.)
2. In a November 4th press release, Defendants explained that "DMC drew no conclusions about OS, the primary endpoint of the OPTIMA study, because the median time that OPTIMA trial participants had been followed was only 25 months, not long enough to draw conclusions. (FAC. ¶ 49.)
3. In a November 14th press release, Defendants stated that the DMC's analysis demonstrated that "progression-free survival (PFS) and overall survival (OS) data appear to be tracking with patient data observed at a similar point in the" HEAT trial "upon which the OPTIMA Study is based." (FAC. ¶ 50.) Further, Defendants informed investors that target for the next DMC's interim analysis would be a hazard ratio of 0.70. *Id.*
4. During a quarterly conference call on November 15th, Defendants stated that the DMC "found no evidence of futility or any safety issues of concern." (FAC. ¶ 51.) But, further explained that although "we did not meet the required hazard ratio at the first interim analysis . . . the science, the medical results, and the preclinical evidence are all compelling . . . even to the skeptic members of the Flat Earth Society." *Id.*

On March 3, 2020, Celsion entered into a Securities Purchase Agreement with four institutional investors, agreeing to sell almost 4.6 million shares for $1.05 per share, grossing $4.8 million. (FAC. ¶ 52.) Plaintiffs allege that by March of 2020, data existed that would prevent the OPTIMA trial from reaching its primary endpoint. (FAC. ¶ 53.) Specifically, Plaintiffs allege that between September 2019 and March 2020, there were 26 consecutive trial participant deaths, in a pattern significantly different than those that preceded the first interim analysis. *Id.* On April 15, 2020, Celsion issued a press release in which it expressed optimism for the DMC's second interim analysis, but that no conclusion could be drawn concerning Median Overall Survival for the OPTIMA trial following the DMC's first interim assessment. (FAC. ¶ 55.)

On May 15, 2020, Defendants revealed that the DMC would be conducting its next interim analysis. (FAC. ¶ 57.) Defendants stated that there is "very good potential for success at this

analysis," and that "the study is on track for success." *Id.* Additionally, Defendants shared that, "Celsion is in excellent financial shape with sufficient capital to fund operations through the second quarter of 2021." *Id.* During a quarterly call on May 15, 2020, Defendants expressed optimism for the DMC's second interim results and stated that if, "tomorrow we were to have a positive result from the DMC, we would immediately place a call to the FDA [and tell them that we] would like to have a pre- NDA meeting with them … then we submit a formal letter to the FDA requesting that meeting, and we're drafting that letter as we speak." (FAC. ¶ 58.) On May 20, 2020, Celsion's stock price increased from $1.48 to $1.72 on volume of 3.6 million. (FAC. ¶ 60.) On May 21, 2020, the price increased to $2.35 on volume of 7.3 million. *Id.* And on May 22, 2020, the price increased to $3.03 on volume of 22.6 million shares. *Id.* On June 15, 2020, Celsion held its annual shareholder meeting, and Defendants stated that "our confidence is quite good for a positive result at this meeting of the DMC." (FAC. ¶ 61.) Following the shareholders meeting, Celsion's stock price and volume increased again. (FAC. ¶ 62.) Between June 9, 2020 and June 19, 2020, the stock price rose from $2.77 to $5.26, on total volume of over 50.5 million shares. *Id.*

On June 22, 2020, Celsion filed a Prospectus with the Securities Exchange Commission ("SEC") concerning the sale of 2,666,6667 shares of Celsion stock through underwriter Oppenheimer & Co. (FAC. ¶ 71.) On July 13, 2020, Celsion issued a press release and stated that Celsion had received the DMC's recommendation, and the DMC recommended stopping the OPTIMA trial. (FAC. ¶ 73.) Defendants expressed their disappointment regarding the DMC's recommendation but shared that they would not be discontinuing the OPTIMA trial. *Id.* Consequentially, Celsion's price fell $2.29 per share, or 63.97%, to close at $1.29 per share. (FAC. ¶ 74.)

On July 15, 2020, Defendants shared that Celsion was now unblinded, and stated that "there is but a very slim chance that the study will meet its prespecified target for success." (FAC. ¶ 75.) After attempts to find an alternative explanation of the results of the OPTIMA trial, on February 11, 2021, Celsion issued a letter to its shareholders informing them that the OPTIMA trial will be discontinued. (FAC. ¶ 81.)

As the Lead Plaintiff, Taraba filed the instant lawsuit as a putative class action, seeking damages for Defendants alleged violations of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), Rule 10b-5, and Section 20(a) of the Exchange Act. (ECF No.1.) On May 27, 2021, Taraba filed the First Amended Complaint. (ECF No. 19.)

II. LEGAL STANDARD

To withstand a motion to dismiss under Rule 12(b)(6), a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint is plausible on its face when there is enough factual content "that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although the plausibility standard "does not impose a probability requirement, it does require a pleading to show more than a sheer possibility that a defendant has acted unlawfully." *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 786 (3d Cir. 2016) (internal quotation marks and citations omitted). Accordingly, a complaint will survive a motion to dismiss if it provides a sufficient factual basis such that it states a facially plausible claim for relief. 556 U.S. at 678.

III. JURISDICTION

As a preliminary matter, the Court that it has subject matter jurisdiction over this matter under 28 U.S.C. § 1331, Section 27 of the Exchange Act.

IV. DISCUSSION

A. Judicial Notice

First, the Court must determine which exhibits are proper to consider at this stage. Pursuant to Federal Rules of Evidence 201, Defendants request that this Court take judicial notice of Exhibits A through K. (Notice Br., ECF No. 28-5.) In opposition, Plaintiff argues that the Court is not permitted to take judicial notice of Exhibits F through H and Exhibits J and K. (ECF No. 31.)[1]

When deciding a motion to dismiss, the Court "generally consider[s] only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014). An exception to this general rule is that a court may consider "a document integral to or explicitly relied upon in the complaint," without converting the motion to dismiss into a motion for summary judgment. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (citation omitted) (emphasis in original). Thus, a court should not consider "evidence outside the amended complaint unless (1) the document is incorporated by reference, or (2) the adjudicative fact at issue is subject to judicial notice." *Institutional Inv'rs Grp. V. Avaya, Inc.*, 564 F.3d 242, 260 n.31 (3d Cir. 2009).)

Here, Defendants argue that the Exhibits in contention are subject to judicial notice because Exhibits F through H represent articles published online or in medical journals, and Exhibits J and K are documents filed with or published by the FDA. Notice Br. at 4–5. In security action matters, the Third Circuit permits courts to take judicial notice of news articles at a Motion to Dismiss

[1] Plaintiff does not oppose the Court to take judicial notice of Exhibits A, B, C, D, E, I, however, clarifies that the Court should not consider the contents of these documents for the truth of "facts." Notice Opp'n Br. at 5. Exhibit A is Celsion's November 14, 2019 10-Q filed by Celsion with the SEC. (ECF No. 28-6, ¶ 2.) Exhibit B is Celsion's 2019 10-K filed by Celsion with the SEC. *Id.* at ¶ 3. Exhibit C is Celsion's 2020 10-K filed by Celsion with the SEC. *Id.* at ¶ 4. Exhibit D is Celsion's May15, 2020 10-Q filed by Celsion with the SEC. *Id.* at ¶ 5. Exhibit E is Celsion's Prospectus Supplement filed by Celsion with the SEC. *Id.* at ¶ 6. Exhibit I is a chart reflecting Celsion's stock price from January 2019 through December 2020. *Id.* at ¶ 10.

stage. *See Benak v. Alliance Cap. Mgmt. L.P.*, 435 F.3d 396, 401 n.15 (3d Cir. 2006). The articles, however, "serve only to indicate what was in the public realm at the time [they were published], not whether the contents of those articles were in fact true." *Id*. Notwithstanding, Plaintiff argues that such Exhibits are "completely extraneous to the pleadings" and are not mentioned in the filed FAC. Notice Br. at 5. In reply, Defendants explicitly underscore that Exhibits F through H and Exhibits J and K are being submitted solely for the fact of their publication, and "only to indicate what was in the public realm at the time, not whether the contents of those articles were in fact true." Notice Reply Br. at 7. Accordingly, because there is no dispute that the Exhibits only serve to the Court as a mere indication of the Exhibits existence in the public realm, the Court will take judicial notice of Exhibits A through K.[2]

B. Section 10(b) of the Exchange Act

Section 10(b) of the Exchange Act makes it "unlawful for any person . . . [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe . . . ." 15 U.S.C. § 78j(b). It is thus, "unlawful for any person . . . [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . ." 17 C.F.R. § 240.10b-5(b).

[2] Additionally, Plaintiff argues that the Court should not consider Defendants' Exhibits 1–16, which are attached to the instant Motion to Dismiss. ECF No. 28-2. Plaintiff argues that Exhibits 12 and 15, are in fact, not even relied upon in Defendants' Motion. But, when a document is explicitly relied upon in the complaint, the document may be incorporated if the claims in the complaint are 'based' on an extrinsic document." *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 368 n.9 (3d Cir. 1993). Defendants have carefully demonstrated to the Court that Exhibits 1–16 are explicitly replied upon in Plaintiff's FAC, and further serve as a basis for Plaintiff's claims. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426; See ECF No. 28-2. Because the primary purpose of the incorporation by reference doctrine is to provide courts with the full context of these isolated quotes, *In re Aetna Sec. Litig.*, 617 F.3d at 285, n.12., the Court will incorporate Exhibits 1–16, without converting the instant Motion to Motion for Summary Judgment.

To bring an action under Section 10(b) and Rule 10b-5 a plaintiff must plead: "(1) a material misrepresentation or omission by the defendant: (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37 (2011). Insofar as actions under Section 10(b) and Rule 10b-5 are inherently based on allegations of fraud, Rule 9(b) imposes a heightened pleading requirement. *In re Rockefeller Ctr. Props.*, Inc. Sec. Litig., 311 F.3d 198, 216 (3d Cir. 2002). Pursuant to Rule 9(b), when "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake ... [m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Further, the Private Securities Litigation Reform Act ("PSLRA") requires an even higher pleading standard for plaintiffs bringing private securities fraud actions. 15 U.S.C § 78u, et seq. A plaintiff must "(1) specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading, 15 U.S.C. § 78u-4(b)(1), and (2) state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind,' § 78u-4(b)(2)."

Here, Defendants argue that Plaintiff has failed to plead all essential elements of Section 10(b), and as follows without a primary violation of Section 10(b) a violation of Section 20(a) fails. Moving Br. at 30.

1. Material Misrepresentation

To successfully plead materiality, a plaintiff must "identify a false representation of material fact or omission that makes a disclosed statement materially misleading." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1419 (3d Cir. 1997)). "[A] fact or omission is material only if there is a

substantial likelihood that it would have been viewed by the reasonable investor as having significantly altered the "total mix" of information available to the investor." *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988) (internal citations omitted). A court must "examine statements in the full context of the documents which they are a part" and not engage in a "selective reading" of the statements. *Burlington Coat Factory*, 114 F.3d at 1426.

Defendants argue that Plaintiff has failed to adequately allege that any of Defendants' statements were false or misleading, and in the alternative provide that Defendants' statements are protected under the PLSRA's Safe Harbor exemption. Moving Br. at 17. Defendants explain that the challenged statements alleged in the FAC are "inactionable puffery" and forward-looking. *Id*. Most importantly, Defendants underscore that Plaintiff's allegation of misrepresentation is fundamentally flawed because the results of the OPTIMA trial were blinded until July 9, 2020. *Id*. In other words, Defendants reason that the mere existence that such data existed when their statements were made does not sufficiently demonstrate that Defendants knew their optimistic statements regarding the OPTIMA trial were false or misleading. *Id*. at 18. Accordingly, in order for Plaintiff's claim to be plausible Defendants argue that the FAC would need to plead that there was a conspiracy to violate FDA protocols and basic standards of scientific integrity to secretly leak the blinded data. *Id*. at. 3. Defendants ultimately characterize their statements as mere opinions because the FAC does not offer any factual support that shows that the statements made by Defendants were not genuinely believed. *Id*. at 21.

In opposition, Plaintiff argues that Defendants improperly read the FAC to allege that Defendants were unblinded to the results from the DMC, Opp'n Br. at 11. Plaintiff states that,

> Plaintiff is unaware whether someone unblinded the results from the second interim data set to Defendants. Defendants expend effort improperly submitting extraneous materials to show the Court what "double blind" means and to prompt it to rule that because it means

> blind, it must be so in this case. The problem for Defendants is that the Complaint does not plead, in any way whatsoever, that someone unblinded the results to Defendants during the Class Period. The Court will therefore accept as true at the pleading stage that Defendants were not unblinded.

Id. at 20. Plainly stated, Plaintiff concedes that Defendants were blinded and unaware of the data for the OPTIMA trial but allege that because the second interim DMC's analysis were complete Defendants' statements regarding anything optimistic about the OPTIMA trial were unreasonable. *Id*. at 13. Plaintiff encourages the Court to examine *Omnicare* for argumentative support. *Id*. at 19; *See Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*. 575 U.S. 175, 189 (2015).

In *Omnicare*, the Supreme Court held that an opinion statement may give rise to liability under the securities laws if it is not believed by the speaker and contains an embedded assertion of incorrect facts. 575 U.S. 175, 185–86 (2015). If the speaker omits facts concerning the basis for the opinion and "those facts conflict with what a reasonable investor would take from the statement itself," the speaker may be liable. *Id*. at 189. Accordingly, "[o]pinions are only actionable … if they are not honestly believed and lack a reasonable basis." *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 543 F.3d 150, 166 (3d Cir. 2008).

The Court disagrees with Plaintiff's reasoning that, "*Omnicare* stands squarely for the proposition that Defendants were required to refrain from positively characterizing the prospects for positive second interim analysis results or for FDA approval." Opp'n Br. at 14. While Defendants did express routine optimism regarding the success of the OPTIMA trial, once the data became unblinded, Defendants stated that "there is but a very slim chance that the study will meet its prespecified target for success." (FAC. ¶ 75.) In examining Defendants' statements in the full context, Plaintiff has not pled how Defendants' statements would have misled a reasonable

investor. *Burlington Coat Factory,* 114 F.3d at 1426. Plaintiff has failed to allege facts that show that Defendants' statements were in fact misrepresentations, and that the supporting facts therein were untrue. *See Omnicare*, 575 U.S. 175, 185–86 (2015).

2. Scienter

Scienter is as an "intent to deceive, manipulate or defraud." *Tellabs, Inc.*, 551 U.S. at 313. To allege scienter, Plaintiff must plead "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id*. A "strong" inference is not "merely reasonable or permissible," it must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Fain v. USA Techs., Inc.*, 707 F. App'x 91, 95 (3d Cir. 2017) (quoting *Tellabs, Inc.*, 551 U.S. at 324). Scienter can be established through knowledge or recklessness. *See Fain*, 707 F. App'x at 96. The relevant inquiry for recklessness is whether defendants "should have known that they were misrepresenting material facts related to the corporation[,]" i.e., when defendants had "knowledge of facts or access to information contradicting their public statements." *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001).

Defendants argue that Plaintiff has failed to pled scienter. Moving Br. at 27. Defendants reason that because a reckless statement is one that is an "extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it," *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 242 (3d. Cir. 2013), Plaintiff has failed to pled that Defendants committed any act and or statements with a conscious or reckless intent to defraud. Moving Br. at 28. Defendants reiterate that Plaintiff cannot and does not allege that Defendants had access to the data at the time such statements were made. *Id*. Moreover, Defendants argue that their statements regarding the

promising implications of ThermoDox, parallel the views shared by publicly available medical articles, and therefore their statements were not an extreme departure from held beliefs. *Id*. As explained above, the Court does not rely on the contents of the articles for the truth of the matter asserted, but merely acknowledges that such articles existed in the public domain.

In opposition, Plaintiff argues that Defendants' statements were an extreme departure from "ordinary care," because Defendants did not affirmatively know the results of the second interim analysis, and thus expressing anything other than proven facts was reckless. *Id*. at 21. Moreover, Plaintiff argues that Defendants' acted with the requisite intent by citing to the fact that Defendants raised an estimated $10 million by selling shares at $3.75. Opp'n Br. 23–24

At this stage, the Court must weigh the "plausible nonculpable explanations for the defendant's conduct" against the "inferences favoring the plaintiff." *Tellabs*, 551 U.S. at 324. Although, Plaintiff continues to argue that focusing on whether the results were unblinded or blinded to Defendants is frivolous, the Court disagrees. Opp'n Br. at 19. The Court finds that this saliently demonstrates that Defendants did not have the knowledge of the data, nor was the data so obviously knowing to render that their statements were made with scienter. *See Wilson v. Bernstock*, 195 F.Supp. 2d 619, 639 (D.N.J. Jan. 2002). Moreover, Plaintiff's attempt to plead scienter by citing Defendants' revenue increase is insufficient. *See GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004) (finding that a desire to raise funds is insufficient to plead motive.) Accordingly, because the FAC is devoid of facts illustrated of Defendants' fraudulent intent, Plaintiff has failed to plead the requisite element of scienter.[3]

[3] Thus far, the Court finds that Plaintiff has failed to successfully plead (1) a material misrepresentation or omission by the defendant and (2) scienter. In the context of 10b–5 claims, elements 4 and 6 – reliance and loss causation – require a plaintiff to allege sufficient facts to show that "the alleged misrepresentations proximately caused the decline in the security's value." *Semerenko v. Cendant Corp.*, 223 F.3d 165, 185 (3d Cir. 2000); see also 15 U.S.C. § 78u–4(b)(4) ([i]n any private action arising under the PSLRA, "the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages.") Accordingly, because loss of causation and reliance inherently require that a plaintiff prove that the

C. Section 20(a)

To survive a motion to dismiss, a plaintiff bringing an action under Section 20(a) must plead: "(1) an underlying primary violation by a controlled person or entity; (2) that [the defendants] exercised control over the primary violator; and (3) that the [d]efendants, as controlling persons, were in some meaningful sense culpable participants in the fraud." *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 642 (D.N.J. 2002). Further, liability under Section 20(a) is predicated upon an independent violation of [the Exchange Act] or the rules or regulations thereunder." *Id*. (internal quotation marks omitted) (quoting *In re Party City Secs. Litig.*, 147 F. Supp. 2d 282, 317 (D.N.J. 2001)). A plaintiff may bring a cause of action against individuals who control a corporation that has violated Section 10(b). 15 U.S.C. § 78t(a) but "liability under Section 20(a) is derivative of an underlying violation of Section 10(b) by the controlled person." *Avaya*, 564 F.3d at 252.

Plaintiff argues that without a primary violation of Section 10(b), a violation of Section 20(a) fails. Moving Br. at 30. The Court agrees. Plaintiff has failed to sufficiently plead a claim under Section 10(b), and accordingly, Plaintiff has failed to plead a Section 20(a) claim. The Court will dismiss Plaintiff's Section 20(a) claim.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss (ECF No. 28) and Request for Judicial Notice (ECF No. 28-5) will be GRANTED and the First Amended Complaint will be

---

defendant's misrepresentation (or other fraudulent conduct) proximately caused the plaintiff's economic loss and that such reliance occur, *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 at 577 (2005), the Court declines to discuss the remaining elements because Plaintiff has failed to plead Defendants' misrepresentation.

dismissed without prejudice. Plaintiff will be given leave to file a Complaint remedying the defect identified within 30 days. An appropriate Order will follow.

Date: **February 6, 2023**

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE